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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,368	12/21/2001	Catherine C. Thompson	P 0283266	3991
909	7590	07/20/2004	EXAMINER	
PILLSBURY WINTHROP, LLP			CARLSON, KAREN C	
P.O. BOX 10500			ART UNIT	
MCLEAN, VA 22102			PAPER NUMBER	

1653

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/024,368

Applicant(s)

THOMPSON

Examiner

Karen Cochran Carlson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on June 1, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9,20-22,24-28,30,31 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9,21,22,24,28,30,31 and 33 is/are rejected.
- 7) ☒ Claim(s) 20 and 25-27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Applicant's election with traverse of Invention I (Claims 19-21; polypeptide) in the paper filed June 1, 2004 is acknowledged. The traversal is on the ground(s) that Applicants wish claims directed to methods of using the elected product rejoined if the product is allowed. This is found persuasive and therefore these method claims will also be examined.

Claims 10-19, 23, 29 and 32 have been canceled. Claims 1-9, 20-22, 24-28, 30, 31, and 33 are currently under examination.

Priority is to April 7, 1998.

The disclosure is objected to because of the following informalities: The application cross reference at page 1 must be updated to reflect that '354 is now a patent.

Appropriate correction is required.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22, 24, 28, 30, 31, and 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-19 of U.S. Patent No. 6,348,348. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent Claims 17-19 encompass the instant invention.

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For example, Claim 17 of the patent is drawn to a method for screening a chemical agent which modulates Hairless transcriptional activity by incubating at least one chemical agent with a transfected cell that expressed the polypeptide of SEQ ID NO: 2 (and variants) and then measuring transcriptional activity. This step corresponds to Claim 22 (a) because transcriptional activity is art-recognized to be assessed by measuring either gene transcription or gene product, which is encompassed in the term "reporter gene". The other steps are the same.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 20-22, 24-28, 30, 31, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, it is not clear what the stringent hybridization conditions are, and the specification does not appear to define the parameters of these conditions. Further, it is not clear what is meant by "wherein the sequence is at least 50 nucleotides in length" when the lowest length of sequence is 225 (75x3 at 1c).

In Claim 21, it is not clear what type of transcription factor activity that the polypeptide is to have.

Claim 24 is redundant because the method of Claim 22 is not stated to be in vivo and because Claim 22 is drawn to a method using a chemical agent, Hairless, and a reporter construct it is inherently in vitro.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4, 6, 7, 9, 20, 21, 22, 24-28, 30, 31, and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not teach variants of SEQ ID NO: 2 having activity. Therefore, the specification lacks written description of variants of SEQ ID NO: 2.

Applicants may overcome this rejection by amending claim 1 with the limitations of Claim 2, for example, "wherein the polypeptide has hairless transcription factor activity".

Note that declarations presented in the parent application do not carry over to this application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) he has abandoned the invention.

Claims 1-4, 6, 7, 9 and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Ahmad et al. (Jan. 30, 1998; Science 279:720-724). Ahmad et al. teach the human hairless

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polypeptide having 99.9% identity to SEQ ID NO: 2 (Fig. 4A). This polypeptide sequence is encoded by a polynucleotide sequence that shares 99.5% identity with SEQ ID NO: 1. Therefore, Ahmad et al. teach a polypeptide that is encoded by a polynucleotide sequence that hybridizes to SEQ ID NO: 1, is greater than 98% identity to SEQ ID NO: 1, and encodes at least 75 contiguous amino acids of SEQ ID NO: 2. (Claims 1, 3, 4, 6, 7, 9).

Ahmad et al. states that this polypeptide is homologous to the murine hairless transcription factor and therefore it is inherent that the polypeptide has Hairless transcription factor activity (Claims 2, 21).

Claims 1, 2, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cachon-Gonzalez et al. (1994; PNAS 91:7717-7721). At page 6 of the specification, conservative changes in amino acids sequence may be considered in determining sequence similarity. Cachon-Gonzalez et al. teach murine hairless gene and gene product. This gene would be considered to hybridize to the nucleotide sequence depicted in SEQ ID NO: 1 (Claims 1a, 2, 9).

Claims 1-9 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson (Dec. 15, 1996; J. Neurosci. 16(24):7832-7840) or under 35 U.S.C. 102(c) because the invention has been abandoned. At page 7839, col. 2, Thompson teaches "*hr* has a cluster of six cysteines with novel spacing that is conserved among mouse, rat, and human (Cachon-Gonzalez et al., 1994; my unpublished observations)". Cachon-Gonzalez et al. teach the mouse *hr* sequence. Thompson teaches the rat *hr* sequence in this reference. Therefore, "my unpublished observations" is that of the human *hr*, clearly teaching that Thompson was in possession of the human *hr*. Because Thompson is the inventor of this claimed invention, and because she had possession of the invention over 1 year before filing provisional application SN 60/080888, it

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appears that the invention had been abandoned because the application for patent was not diligently filed.

There is found a discussion of 35 U.S.C. 102(c) at M.P.E.P. 2134. Under 35 U.S.C. 102(c), AN ABANDONMENT MUST BE INTENTIONAL. "Actual abandonment under 35 U.S.C. 102(c) requires that the inventor intend to abandon the invention, and intent can be implied from the inventor's conduct with respect to the invention. In re Gibbs, 437 F.2d 486, 168 USPQ 578 (CCPA 1971).

Abandonment under 35 U.S.C. 102(c) requires a deliberate, though not necessarily express, surrender of any rights to a patent.

**To abandon the invention the inventor must intend a dedication to the public.** Such dedication may be either express or implied, by actions or inactions of the inventor. Because Applicant published and therefore made public the fact that she was in possession of human *hairless* in 1996, it can be concluded that human *hairless* was intended to be dedicated to the public.

**Delay alone is not sufficient to infer the requisite intent to abandon.** Moore v. United States, 194 USPQ 423, 428 (Ct. Cl. 1977) (The drafting and retention in his own files of two patent applications by inventor indicates an intent to retain his invention; delay in filing the applications was not sufficient to establish abandonment); but see Davis Harvester Co., Inc. v. Long Mfg. Co., 252 F. Supp.989, 1009-10, 149 USPQ 420, 435-436 (E.D. N.C. 1966) (Where the inventor does nothing over a period of time to develop or patent his invention, ridicules the attempts of another to develop that invention and **begins to show active interest in promoting and developing his invention only after successful marketing by another of a device embodying that invention, the inventor has abandoned his invention under 35 U.S.C.102(c).**). Applicant did not retain human *hairless* privately as demonstrated by the fact that Applicant made public the fact that she was in possession of human *hairless* in 1996. Further, after the publication of Ahmad et

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al. and Cichon et al. in 1998, each teaching human *hairless* for the treatment of alopecia, Applicant filed SN 60/ 080,888. See Applicant's citation of Ahmad et al. and Cichon et al. at pages 3, 5, and 44, Table II at page 45, and Figs 1A-1M, for example.

Claims 20 and 25-27, are objected to for being dependent on a rejected base claim.

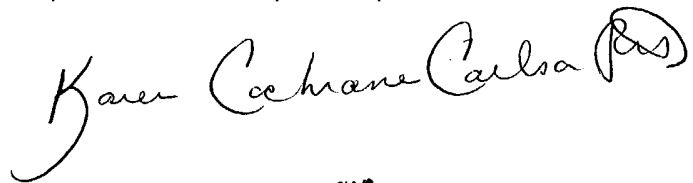
No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in cursive script that reads "Karen Cochrane Carlson" followed by a stylized monogram or initials.

KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER